The U.S. Food and Drug Administration (FDA) employs a risk-based approach to regulating medical technology where the level of requirements to determine a device or diagnostic’s safety and effectiveness is commensurate to its risk.

**Premarket Requirements**

**Class I: Low Risk**
- Bandages
- Examination Gloves
- Most exempt from premarket submission requirements

**Class II: Moderate Risk**
- Contact Lenses
- Ultrasound Scanners
- X-Ray Machines
- Artificial Heart Valves
- Defibrillators

**Class III: High Risk**
- Spinal Implants

**Premarket Clearance 510(k)**
Must demonstrate "substantial equivalence" to one or more devices legally marketed in the U.S.

Information in a 510(k) submission includes:
- Bench Testing
- Animal Studies (if deemed necessary by FDA)
- Batteries of non-clinical tests (biocompatibility, shelf-life, shock and vibration, temperature cycling, etc.)
- Tests demonstrating conformance with relevant national and international standards
- Any additional requirements specified by FDA, including clinical studies

**Premarket Approval Applications (PMA)**
Must establish a "reasonable assurance of safety and effectiveness" as demonstrated by valid scientific evidence.

A complete PMA application will include:
- Results of any clinical studies
- Description of manufacturing & processing
- Description of the device including components, ingredients, properties, and principles of operation
- Full reports of all known information on the device’s safety and effectiveness
- Results of non-clinical trials (bench/animal testing)
- Proposed professional and patient labeling
- A summary of safety and effectiveness data
All manufacturers of medical devices and diagnostics approved or cleared for marketing in the U.S. must comply with the following requirements:

**Quality Systems:**
Companies must have processes and procedures in place to ensure products are manufactured consistently according to pre-determined specifications for safety and effectiveness.

**Registration and Listing:**
Facilities involved in the manufacture and distribution of medical devices in the U.S. must register annually with FDA and list the products and activities performed at those facilities.

**Medical Device Reporting:**
Manufacturers must report to FDA any device-related incidents, deaths, serious injuries, and device malfunctions which are likely to cause or contribute to death or serious injury if they were to occur.

**Recalls:**
Companies must report to FDA any correction or removal from the market of a medical device intended to reduce a risk to the public health.

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**Certain Class II and Class III devices can be subject to additional postmarket requirements:**

**Tracking**
FDA may order manufacturers to adopt a method of tracking for devices whose failure would be reasonably likely to have serious, adverse health consequences; or which is intended to be implanted in the human body for more than one year; or are life-sustaining or life-supporting devices used outside of a device user facility.

**Postmarket Surveillance**
FDA can require a manufacturer to conduct a range of activities involving the collections and analysis of data on a marketed device related to anticipated or unforeseen adverse events or other information necessary to protect the public health and safety.

**Condition of Approval Studies**
As a condition of marketing approval for a Class III device, FDA can require continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use.